CLAIM SUMMARY DOCUMENT

Claim 1 (Previously Presented) A process for producing a peptide having a desired biological activity, comprising the steps of:

(1) culturing cells transformed with an expression vector having a nucleotide sequence encoding a peptide of interest that has a helper peptide added thereto, and then harvesting said peptide of interest that has a helper peptide added thereto from said culture, wherein the helper peptide has 5 to 50 amino acid residues and is designed so that the isoelectric point of the peptide of interest that has helper peptide added thereto is between 8 and 12;

(2) cleaving off from the peptide of interest that has the helper peptide added thereto obtained in step (1), the helper peptide and the peptide of interest; and

(3) purifying the peptide of interest obtained in step (2).

Claims 2-5 (Canceled)

Claim 6 (Previously Presented) The process according to claim 1, wherein an ion exchange resin is used in the purification process.

Claim 7 (Original) The process according to claim 6, wherein said ion exchange resin is a cation exchange resin.

Claim 8 (Previously Presented) The process according to claim 1, wherein a reverse phase chromatography or a hydrophobic chromatography is used in the purification process.

Claim 9 (Previously Presented) The process according to claim 1, wherein a surfactant and/or a salt are added in at least one of steps (1) to (5) to maintain the solubility of the peptide of interest.

Claim 10 (Previously Presented) The process according to claim 1, wherein the host cell is a prokaryotic cell or a eukaryotic cell.

Claim 11 (Original) The process according to claim 10, wherein the host cell is *Escherichia coli*.

Claim 12 (Canceled)

Claim 13 (Previously Presented) The process according to claim 1, wherein the peptide of interest is an amidated peptide.

Claim 14 (Previously Presented) The process according to claim 1, wherein the peptide of interest is a GLP-1 derivative having an insulinotropic activity.

Claim 15 (Canceled)

Claim 16 (Previously Presented) The process according to claim 14, wherein the GLP-1 derivative having an insulinotropic activity has an isoelectric point of 4.5 to 9.0.

Claim 17 (Previously Presented) The process according to claim 14, wherein the GLP-1 derivative having an insulinotropic activity has an isoelectric point of 5.5 to 7.5.

Claim 18 (Previously Presented) The process according to claim 1, wherein an ion exchange resin is used in the purification process.

Claim 19 (Original) The process according to claim 18, wherein said ion exchange resin is a cation exchange resin.

Claim 20 (Previously Presented) The process according to claim 1, wherein a reverse phase chromatography or a hydrophobic chromatography is used in the purification process.

Claim 21 (Previously Presented) The process according to claim 1, wherein a surfactant and/or a salt is added to maintain the solubility of the peptide of interest.

Claim 22 (Previously Presented) The process according to claim 14, wherein the purity of the GLP-1 derivative obtained having an insulinotropic activity is 98% or greater.

Claim 23 (Previously Presented) The process according to claim 1, wherein endotoxin is present in the peptide of interest obtained in step (3), and wherein the content of endotoxin is not greater than 0.03 units/mg.

Claim 24 (Canceled)

Claim 25 (Previously Presented) An expression vector comprising a nucleotide sequence encoding a peptide of interest that has a helper peptide added thereto, wherein the helper peptide has 5 to 50 amino acid residues and is designed so that the isoelectric point of the peptide of interest that has the helper peptide added thereto is between 8 and 12.

Claim 26 (Previously Presented) A prokaryotic or a eukaryotic cell transformed with an expression vector comprising a nucleotide sequence encoding a peptide of interest that has a helper peptide added thereto, wherein the helper peptide has 5 to 50 amino acid residues and is designed so that the isoelectric point of the peptide of interest that has the helper peptide added thereto is between 8 and 12.

Claim 27 (Original) The cell according to claim 26, wherein the host cell is *Escherichia coli*.

Claim 28 (Previously Presented) The process according to claim 1, wherein the peptide of interest obtained in step (2) is subjected to a modification reaction to obtain a modified peptide.

Claim 29 (Previously Presented) A process for producing a peptide having a desired biological activity, comprising the steps of:

(1) culturing cells transformed with an expression vector having a nucleotide sequence encoding a fusion protein that has a protective peptide added to the peptide of interest that has a helper peptide added thereto, and then harvesting said fusion protein from said culture, wherein the helper peptide has 5 to 50 amino acid residues and is designed so that the isoelectric point of the peptide of interest that has helper peptide added thereto is between 8 and 12;

(2) cleaving off from said fusion protein the peptide of interest that has a helper peptide added thereto and the protective peptide, and purifying the peptide of interest that has the helper peptide added thereto as desired;

(3) cleaving off from the peptide of interest that has the helper peptide added thereto obtained in step (2), the helper peptide and the peptide of interest; and

(4) purifying the peptide of interest obtained in step (3).

Claim 30 (Previously Presented) The process according to claim 29, wherein said protective peptide has 30 to 200 amino acid residues.

Claim 31 (Previously Presented) The process according to claim 29, wherein an ion exchange resin is used in the purification process.

Claim 32 (Previously Presented) The process according to claim 31, wherein said ion exchange resin is a cation exchange resin.

Claim 33 (Previously Presented) The process according to claim 29, wherein a reverse phase chromatography or a hydrophobic chromatography is used in the purification process.

Claim 34 (Previously Presented) The process according to claim 29, wherein a surfactant and/or a salt are added in at least one of steps (1) to (5) to maintain the solubility of the peptide of interest.

Claim 35 (Previously Presented) The process according to claim 29, wherein the host cell is a prokaryotic cell or a eukaryotic cell.

Claim 36 (Previously Presented) The process according to claim 35, wherein the host cell is *Escherichia coli*.

Claim 37 (Previously Presented) The process according to claim 29, wherein the peptide of interest is an amidated peptide.

Claim 38 (Previously Presented) The process according to claim 29, wherein the peptide of interest is a GLP-1 derivative having an insulinotropic activity.

Claim 39 (Previously Presented) The process according to claim 38, wherein the GLP-1 derivative having an insulinotropic activity has an isoelectric point of 4.5 to 9.0.

Claim 40 (Previously Presented) The process according to claim 38, wherein the GLP-1 derivative having an insulinotropic activity has an isoelectric point of 5.5 to 7.5.

Claim 41 (Previously Presented) The process according to claim 1, wherein an ion exchange resin is used in the purification process.

Claim 42 (Previously Presented) The process according to claim 41, wherein said ion exchange resin is a cation exchange resin.

Claim 43 (Previously Presented) The process according to claim 1, wherein a reverse phase chromatography or a hydrophobic chromatography is used in the purification process.

Claim 44 (Previously Presented) The process according to claim 1, wherein a surfactant and/or a salt is added to maintain the solubility of the peptide of interest.

Claim 45 (Previously Presented) The process according to claim 38, wherein the purity of the GLP-1 derivative obtained having an insulinotropic activity is 98% or greater.

Claim 46 (Previously Presented) The process according to claim 29, wherein the content of endotoxin in the final purified product is not greater than 0.03 units/mg.

Claim 47 (Previously Presented) The process according to claim 29, wherein the peptide of interest obtained in step (2) is subjected to a modification reaction to obtain a modified peptide.

Claim 48 (Previously Presented) An expression vector comprising a nucleotide sequence encoding a fusion protein that has a protective peptide added to a peptide of interest that has a helper peptide added thereto, wherein the helper peptide has 5 to 50 amino acid residues and is designed so that the isoelectric point of the peptide of interest that has the helper peptide added thereto is between 8 and 12.

Claim 49 (Previously Presented) A prokaryotic or a eukaryotic cell transformed with an expression vector comprising a nucleotide sequence encoding a fusion protein that has a protective peptide added to a peptide of interest that has a helper peptide added

thereto, wherein the helper peptide has 5 to 50 amino acid residues and is designed so that the isoelectric point of the peptide of interest that has the helper peptide added thereto is between 8 and 12.